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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,053	12/29/2006	Peter Schwind	BPD-105US	4352

23122 7590 03/02/2010

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EXAMINER	
WALLENHORST, MAUREEN	
ART UNIT	PAPER NUMBER
1797	
MAIL DATE	DELIVERY MODE
03/02/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/588,053	SCHWIND, PETER	
	Examiner	Art Unit	
	Maureen M. Wallenhorst	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/31/06, 9/14/06, 11/13/06, 9/14/07, 5/4/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

> The oath or declaration is defective because: The filing date of the application listed in the declaration (i.e. July 31, 2006) is incorrect. The correct filing date for the application is December 29, 2006 since this is the date that all requirements of 35 USC 371 were met. Therefore, a new declaration reciting the correct filing date of December 29, 2006 should be filed.

3. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

4. The abstract of the disclosure is objected to because of the inclusion of legal phraseology such as "comprises" and "said". Correction is required. See MPEP § 608.01(b).

5. It is noted that the substitute specification filed on August 6, 2009 has been entered. The change made in the specification from a "blood bottle" to a "blood bag" is acceptable since Applicant has admitted and asserted on the record that the translation of the German priority document into English resulted in the incorrect description of the container in the instant application being called a "blood bottle" instead of the correct "blood bag".

6. Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite since it is not clear what is meant by the "fixing means". Do the fixing means serve to physically attach the test element to another object, or do the fixing means serve to chemically fix the test units on the test element for preservation?

On line 2 of claim 5, the phrase "the test result" lacks antecedent basis.

On line 2 of claim 6, the phrase "the at least two test elements" should be changed to --the at least two test units-- so as to use the same terminology as used in claim 1. This same change should also be made on line 2 of claim 7.

On lines 1-2 of claim 10, the phrase "in which by means of the test unit" should be changed to --in which by means of one of the at least two test units-- so as to make proper sense.

On line 3 of claim 13, the phrase "the first test unit" lacks antecedent basis since independent claim 1 does not refer to first and second test units. Similarly, on line 7 of claim 13, the phrase "the second test unit" lacks antecedent basis. On line 7 of claim 13, the phrase "the receptor" lacks antecedent basis.

On line 2 of claim 14, the phrase "obtaining a first test result", and on line 3 of claim 14, the phrase "obtaining a second test result" lack antecedent basis since claim 13, from which claim 14 depends, fails to recite obtaining any test results. On lines 2-3 of claim 14, the phrase "the receptor blood" lacks antecedent basis. On line 3 of claim 14, the phrase "the test results" lacks antecedent basis.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Friedman et al (US 4,055,394, submitted in the IDS filed on September 14, 2006).

Friedman et al teach of a diagnostic test element suitable for performing a blood typing test for blood groups A, B, AB and O. The test element comprises a sheet or strip of substrate material 11 divided into two portions, namely a test surface 12 and a flap or covering portion 20 which is attached along line 21. The test surface 12 contains on its surface two test units 14 for performing two blood type tests. One of the test units 14 contains a solid dried spot of anti-B antiserum 15, and the other test unit 14 contains a solid dried spot of anti-A antiserum 16. The covering portion 20 is provided with convex windows 22 such that when the flap portion 20 is folded over the test surface 12, the windows are in registry with the corresponding test units 14, thus exposing the contents of the test units 14 to view through the windows 22. The underside of the substrate 11 is coated with a layer of adhesive material 19, upon which there is mounted a layer of peelable or strippable material 19a, which has a tab portion 19b that extends beyond edge 18 of the substrate 11 to permit grasping of the strippable member for removal. Removal of the adhesive layer 19 from the underside of the test element 11 allows one to mount the test element to any desired surface. Therefore, the layer of adhesive material 19 on the test element serves as a fixing means for fixing the test element to any desired surface. Friedman et al teach that the reaction products and test results are kept isolated from human contact and possible

infection by outside sources. In addition, the sealed test results can readily be stored and held for future reference and interpretation. Thus, after a blood type test is performed, no fluid emerges from the test element. See Figures 1-4, lines 37-68 in column 2, lines 1-30 in column 3, and lines 29-44 in column 4 of Friedman et al.

9. Claims 1-2 and 6-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Hewett (US 4,851,210).

Hewett teaches of a blood typing device or element for determining whether a blood sample is of type O, type A, type B or type AB. In addition, the device can determine whether a blood sample contains D antigens on the red blood cells and is Rh+, or whether a blood sample lacks D antigens on the red blood cells and is Rh-. The device comprises a support 10 in combination with a water permeable membrane 12 to which antibodies are bound using a linker 14. The device can take the form of a tag 33 that contains membrane pad regions. The pad regions indicated at A, B and D contain surface antibodies specific against blood groups A, B and D (Rh). Figure 4 of Hewett illustrates a tag 33 with five membrane pad areas which are an anti-A antibody area A, an anti-B antibody area B , an anti-D antibody area D, a positive control pad C+ having antibodies against all red blood cells, and a negative control area C- having neutral proteins thereon. The tag 33 is designed for attachment to a blood container to provide a tag on the container identifying the blood type of the contents. Figure 4 depicts a blood bag 32 having the blood-type identification test element 33 adhesively attached to a side of the bag. To use the test element device, a blood sample is collected from a donor into the blood bag 32. Blood from the bag is then applied to the support regions or pads of the tag 33. After incubation for 1-3 minutes, the card is washed. The tag shows strongly colored regions where

immunospecific cell binding has occurred, and uncolored regions for negative reactions. The card is allowed to dry so that no fluid emerges after performance of the blood type test, giving a permanent, easily readable record of blood type. The card is permanently attached, for example, by stapling, clamping or adhesive backing, to the blood bag 32. In this way, a permanent record of assay results is established for the donor blood, so retesting is not required to confirm blood type. Therefore, Hewett teaches of a test element comprising at least two test units for performing at least two tests (i.e. pads A, B and D on tag 33 that perform tests for type A blood antigens, type B blood antigens and type D blood antigens), and a fixing means for fixing the test element to a blood bag (i.e. adhesive on the support 20 of the tag 33). See Figures 1-2, 3a-3b and 4, lines 40-68 in column 1, lines 45-68 in column 7, lines 1-33 in column 8, lines 4-27 in column 9 and lines 35-42 in column 11 of Hewett.

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claims 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hewett. For a teaching of Hewett, see previous paragraphs in this Office action.

Hewett fails to teach that the fixing means for fixing the test element or tag 33 to a blood bag can be a bonding foil or a cable tie. However, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to use an alternative means for fixing the tag 33 to the blood bag taught by Hewett such as a bonding foil or a cable tie in place of the adhesive, staple or clamp taught by Hewett since each of these types of fixing means are all known and equivalent fasteners for attaching two or more objects together, and the substitution of one known means for fixing or fastening objects together (i.e. a bonding foil or a cable tie) for another (i.e. an adhesive, staple or clamp) would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Hewett also fails to teach that the test results produced on the tag or test element 33 after a blood sample is applied to the tag 33 are maintained for at least 45 days. However, it would have been obvious to one of ordinary skill in the art to realize that the test results produced on the tag 33 taught by Hewett would be maintained for at least 45 days since Hewett teaches that a permanent record of blood type results is produced on the tag so that retesting of a blood sample is not required to confirm blood type, and a permanent record inherently means at least 45 days.

13. Claims 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hewett in view of EP 741,296 (submitted in the IDS filed on September 14, 2006). For a teaching of Hewett, see previous paragraphs in this Office action. Hewett fails to teach that the test element or tag 33 has a test area containing anti-A, anti-B and anti-D antibodies thereon for testing the

blood type of a blood transfusion recipient's blood in addition to the test area for testing the blood type of a donor's blood.

EP 741,296 teaches of a pre-transfusion test element for the determination of the compatibility between donor and receiver blood. The test element comprises a number of panels 1, 2 and 3. The central panel 2 has areas 41-44, 51-54 and 61-64 impregnated with dried anti-A and anti-B antibodies thereon. Areas 41, 51 and 61 are intended to receive a drop of blood from a patient receiving a blood transfusion while areas 42-44, 52-54 and 62-64 are intended to receive a drop of blood from a donor in order to determine the blood type of the transfusion recipient and the blood type of the donor. The panel 3 has an adhesive transparent film 30 covered with a protective sheet 31 that is peelable from the film 30. After peeling the sheet 31 from the film 30, the adhesive layer 3 is folded and stuck down over the adjacent panel 2. Therefore, EP 741,296 teaches of a test element containing at least two test areas for performing blood type tests on both the blood of a patient undergoing a blood transfusion and a blood donor. See Figure 1 and the abstract in EP 741,296.

Based upon the combination of Hewett and EP 741,296, it would have been obvious to one of ordinary skill in the at the time of the instant invention to modify the test element or tag 33 taught by Hewett to include test areas for determining the blood type of a blood transfusion recipient in addition to the test areas for determining the blood type of a donor, similar to the test element taught by EP 741,296, in order to consolidate the testing of both a blood donor's and a blood transfusion recipient's blood into one device, thus making it easier to compare the results of the blood typing between the donor and the recipient to ensure accurate test results and

rendering the testing of the donor and recipient's blood less costly and labor intensive, as disclosed by EP 741,296.

14. Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 741,296 in view of Hewett. For a teaching of EP 741,296 and Hewett, see previous paragraphs in this Office action.

EP 741,296 teaches of a test element and a method of use for testing blood during the preparation and performance of a blood transfusion, as substantially claimed. EP 741,296 fails to teach that the test element contains fixing means thereon for fixing the test element to a blood bag. However, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to include fixing means on the test element taught by EP 741,296 for fixing the test element to a blood bag since Hewett teaches that by fixing a test element used for blood typing of a donor's blood sample to a blood bag used to collect the donor blood, one is able to provide a permanent record of the blood type assay results and associate those results with the blood sample tested so that no retesting of the blood sample is required to confirm the blood type held within the blood bag. With regards to claims 3-4, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to use an alternative means for fixing the test element taught by EP 741,296 to a blood bag other than those taught by Hewett such as a bonding foil or a cable tie in place of the adhesive, staple or clamp taught by Hewett since each of these types of fixing means are all known and equivalent fasteners for attaching two or more objects together, and the substitution of one known means for fixing or fastening objects together (i.e. a bonding foil or a cable tie) for another (i.e. an adhesive, staple or clamp) would have yielded predictable results to one of ordinary skill in the art at the time of the invention. With

regards to claim 5, it would have been obvious to one of ordinary skill in the art to realize that the test results produced on the test element taught by EP 741,296 would be maintained for at least 45 days since the test element taught by EP 741,296 serves to close and cover the assay regions on the panel 2, thus preserving their reaction results for a long period of time of time, including at least 45 days.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Thursday from 6:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim, can be reached on 571-272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1797

mmw

February 24, 2010

/Maureen M. Wallenhorst/

Primary Examiner, Art Unit 1797